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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,641	12/17/1998	TERRY LEE BURKOTH	7010-0001	9355

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	23

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/216,641	BURKOTH ET AL.	
	Examin r	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26 and 28-40* is/are rejected.

7)☒ Claim(s) *27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *22*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/03 has been entered.

Claims 1-40 are pending in the present application, with claims 1-14 being withdrawn because they are drawn to non-elected invention.

Amended claims 15-40 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 15-26, 28-30, 32-37 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

(1) A method for forming densified particles from a particulate pharmaceutical preparation containing a peptide or a protein, comprising compacting the preparation in a press to provide a compacted pharmaceutical preparation and size-reducing the compacted preparation into densified particles of suitable size and density for transdermal delivery thereof by needleless injection; the same densified or compacted

particular pharmaceutical composition and a unit dosage container for a needleless syringe comprising the same;

(2) A method of delivering a selected pharmaceutical agent to a vertebrate subject, said method comprising providing a compacted particulate pharmaceutical preparation according to claim 37, said preparation comprising the pharmaceutical agent and transdermal delivering the preparation to a target tissue or cell of the vertebrate subject by needless syringe, wherein said pharmaceutical agent is a peptide or a protein;

does not reasonably provide enablement for a method for forming densified particles from a particulate preparation containing a gene construct, a unit dosage container for a needleless syringe comprising the same, and a method of delivering a compacted particulate pharmaceutical composition of the present invention to a vertebrate subject by needless syringe via any route of delivery and the same wherein said pharmaceutical composition contains a gene construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This rejection contains a new ground of rejection.**

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte*

Forman, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The claims are drawn to a method for forming densified particles from a particulate pharmaceutical preparation, comprising compacting the preparation in a press to provide a compacted pharmaceutical preparation and size-reducing the compacted preparation into densified particles of suitable size and density for transdermal delivery thereof by needleless injection; a densified particulate pharmaceutical composition having the properties recited in claim 29 or claim 37; a unit-dosage container for a needleless syringe comprising the same compacted particulate pharmaceutical preparation; and a method of delivering a selected pharmaceutical agent to a vertebrate subject by delivering the compacted particulate pharmaceutical preparation to a target tissue or cell of the vertebrate subject by needless syringe.

The specification discloses the preparation of compositions comprising pGREEN-1 vector or a human growth hormone (hGH) encoding or β-galactosidase encoding expression plasmid vector in the presence of trehalose sugar excipient, which were compressed, ground and sieved to form condensed nucleic acid compositions. The compositions were individually administered through a needleless injection device to target skin surfaces of either C57BL/10 mice or female pigs. After 24 hours of administration, biopsy samples revealed GFP and β-galactosidase expression in treated sites, whereas hGH expression was not detected. The lack of hGH expression was attributed to the low loading density of the nucleic acid in the composition (See example 2). The specification further teaches the preparation of a densified composition

comprising lyophilized recombinant hGH powder (Genotropin), and it demonstrates that in comparison with the lyophilized rhGH powder, a higher proportion of the densified composition penetrated porcine skin by needleless injection. Additionally, the specification teaches that markedly increased blood serum levels of rhGH were obtained in New Zealand White rabbits that were intradermally administered with densified Genotropin particles through the needleless injection system.

The above evidence has been noted and considered. However, the evidence is not reasonably extrapolated to the instant broadly claimed invention for the reasons discussed below.

1. The breadth of the claims

The instant claims encompass a method for forming densified particles from any particulate pharmaceutical preparation including any peptide or any protein or any gene construct pharmaceutical preparation by compacting the preparation in a press to provide a compacted pharmaceutical preparation and size-reducing the compacted preparation into densified particles of suitable size and density for transdermal delivery thereof by needleless injection; the same densified or compacted particulate pharmaceutical preparation or composition; and a method of delivering a selected pharmaceutical agent to a vertebrate subject by delivering the same compacted particulate pharmaceutical preparation to any target tissue or any cell of the vertebrate by needleless injection via any route of delivery.

When read in light of the specification, the sole purpose for a method of delivering as well as a method for preparing a compacted particulate pharmaceutical

preparation containing a gene construct of the present invention is for the purposes of gene therapy and/or genetic immunization (See pages 22-24 of the specification).

2. The state and the unpredictability of the prior art

At about the effective filing date of the present application (6/17/1996), the art of gene therapy and nucleic acid immunization was immature and remains unpredictable for obtaining any therapeutic effects as evidenced by the teachings of Dang et al. (Clin. Cancer Res. 5:471-474, 1999; Cited previously); Chattergoon et al. (FASEB J. 11:753-763, 1997; Cited previously) and Leitner et al. (Vaccine 18:765-777, 2000; Cited previously). In 1999, Dang et al. still state "This workshop reviewed some recent advances in gene delivery, gene expression, immune manipulation, and the development of molecular targets and stressed that all of these fields will need further advancement **to make gene therapy a reality**" (page 471, col. 1, bottom of first paragraph); "Although significant progress has been achieved in our understanding of the limitations of gene therapy by suboptimal vectors, host immunological responses to the vectors, and the lack of long term stable expression, the major challenge that limits clinical translation remains in achieving efficient gene delivery to target tissues" (page 474, col. 2, last paragraph), let alone at the effective filing date of the present application. Chattergoon et al. state that "Though DNA vaccines have shown promise in animal models and have raised hopes, **the technology is considered an emerging technology**" (column 1, paragraph 2, page 762). More recently, Leitner et al. also state "Although genetic vaccines have been significantly improved, **they may not be sufficiently immunogenic for therapeutic vaccination of patients with infectious**

disease or cancer in clinical trials" (Abstract, page 765). Leitner et al. also listed several variable factors affecting the immunogenicity of genetic vaccines. These include: the structure of the plasmid backbone, amount of plasmid delivered, expression levels of the antigen, age and strain of the particular species, target tissue, and route of immunization among others (See Table 1, page 767).

Furthermore, at the effective filing date of the present application (6/17/1996) little was known in the prior art on the attainment of any therapeutic or prophylactic effects via the application of densified particles of a particulate pharmaceutical preparation containing a gene construct of the present invention (without the presence of biolistic core carriers, see specification page 17, lines 3-4) in any vertebrate subject as demonstrated by the teachings of Bellhouse et al. (US Patent 5,630,796); Roser et al. (US Patent 6,331,310) and Johnston et al. (US Patent 6,194,389).

3. The amount of direction or guidance provided

The instant specification is not enabled for the **use** of the instant broadly claimed invention because it fails to provide sufficient guidance for one skilled in the art on how to use a compacted or densified particulate pharmaceutical composition comprising a gene construct of the present invention to obtain any therapeutic effect and/or prophylactic effect contemplated by Applicants. It is unclear whether a gene construct in the densified pharmaceutical preparation of the present invention is still intact and that it is not susceptible to nicks or degradation due to the compacting process under high pressure, or during its delivery to a vertebrate subject by needleless injection. A genetic construct in the form of a nucleic acid or DNA molecule is highly sensitive to

degradation, particularly for a large genetic construct. Applicants have noted that known biolistic techniques are not appropriate for use with large DNA molecules since precipitation of such molecules onto core carriers can lead to unstable configurations that will not withstand the shear forces of gene gun delivery (specification, page 7, line 32 continues to line 2 of page 8). Bellhouse et al. (US Patent 5,630,796) also state "In a further example of the use of the new technique, **not for transdermal injection**, but for the genetic transformation of cells, for example the injection of DNA-coated tungsten carrier particles into maize cells..." (col. 3, lines 57-60). More importantly, there is no correlation between the expression of green fluorescent protein (GFP) or β-galactosidase with any therapeutic and/or prophylactic results for treating a plethora of diseases, disorders, genetic defects such as, AIDS, cancer, neurological diseases, cardiovascular diseases, cystic fibrosis, adenosine deaminase deficiency among many others as contemplated by Applicants (see specification page 22, lines 11-32). There is no evidence of record that a densified pharmaceutical composition comprising a gene construct of the present application could provide any expression of a relevant therapeutic gene product *in vivo* at any level via a needleless injection, let alone a therapeutic expression level. The lone relevant example of a densified particulate pharmaceutical composition of the present application indicated clearly a lack of hGH expression being detected in treated mice or pigs upon administering into the animals a preparation containing an expression plasmid encoding hGH by a needleless injection (See example 2). There are several known factors limiting an effective gene therapy, and these include sub-optimal vectors, the lack of a long-term and stable gene

expression *in vivo*, as well as the lack of an efficient gene delivery to target tissues (Dang et al., 1999). It is also well known in the art that transgene expression *in vivo* is very transient.

Since the prior art at the effective filing date of the present application does not provide such guidance, it is incumbent upon the present application to do so. In the absence of sufficient guidance provided by the present disclosure, and in light of the state and the unpredictability of the prior art, it would have required undue experimentation for a skilled artisan to make and use the full breath of the presently claimed invention.

As set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> That scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the are; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

With respect to claim 40 encompassing the delivery of a compacted particulate pharmaceutical preparation, including one that contains a gene construct, to any target tissue or cell of a vertebrate subject by any route of administration such as intravenous, oral or aerosol deliveries using a needleless syringe. However, apart from the transdermal delivery of the pharmaceutical preparation taught by the present application, the specification fails to provide sufficient guidance for one skilled in the art on how to make and use the method as broadly claimed, especially for achieving any

therapeutic and/or prophylactic effect. Since the prior art at the effective filing date of the present application does not provide such guidance (see Bellhouse et al.; US Patent 5,630,796; Roser et al., US Patent 6,331,310 and Johnston et al.; US Patent 6,194,389), it is incumbent upon the present application to do so. Moreover, with respect to the compacted particulate pharmaceutical preparation containing a gene construct, it should also be noted that *in vivo* vector targeting to desired target tissues or cells was and remains unpredictable as taught by Dang et al., and numerous other arts such as the teachings of Miller et al. (FASEB J. 9:190-199, 1995; Cited previously) and Verma et al. (Nature, 389:239-242; 1997; Cited previously).

Given the lack of sufficient guidance provided by the present application, and the state and the unpredictability of the relevant prior art it would have required undue experimentation for a skilled artisan to make and use the full scope of the method as claimed.

4. The quantity of experimentation provided

There is no example indicating that any therapeutic and/or prophylactic effect has been attained for any densified or compacted particulate pharmaceutical composition comprising any gene construct. Nor is there any example showing any therapeutic and/or prophylactic effect has been attained in a vertebrate subject by any densified or compacted particulate pharmaceutical composition of the instant invention via any other routes of delivery with a needleless syringe other than via transdermal delivery.

Accordingly, due to the lack of sufficient guidance provided by the specification regarding to the issues set forth above, the unpredictability and the current state of the

gene therapy and/or nucleic acid immunization art, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and **use** the instant broadly claimed invention.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 7/16/03 in Paper No. 19 (pages 4-8) have been fully considered, but they are not found persuasive.

1. Applicants argue that Applicants do not claim a method for gene therapy, but to methods for converting existing pharmaceutical preparations into a form suitable for administration from a needleless syringe delivery device and methods for delivering these compacted pharmaceuticals. Additionally, the specification has been provided, complete with numerous working examples, all detailing how to carry out the recited invention including a variety of uses for the compacted pharmaceuticals.

Please note that the sole purpose for a method of delivering as well as a method for preparing a compacted particulate pharmaceutical preparation containing a gene construct of the present **invention is for the purposes of gene therapy and/or genetic immunization** (See pages 22-24 of the specification). The instant specification fails to provide a single example demonstrating that an expression of a therapeutic gene has been attained in any vertebrate using a densified or compacted particulate pharmaceutical composition comprising a gene construct of the present invention, let alone for attaining any therapeutic and/or prophylactic effect contemplated by

Applicants. The lone relevant example of a densified particulate pharmaceutical composition of the present application indicated clearly a lack of hGH expression being detected in treated mice or pigs upon administering into the animals a preparation containing an expression plasmid encoding hGH by a needleless injection (See example 2). Furthermore, the attainment of any therapeutic and/or prophylactic effect via gene therapy and/or nucleic acid immunization **is neither routine experimentation nor predictable** as evidenced by numerous articles cited above.

2. Applicants further argue that as at Applicants' filing date, there were numerous gene therapy pharmaceuticals that skilled artisans were administering to human subjects in various clinical trials. It is well within the capacity of the skilled artisan to select a gene therapy composition that has been shown to work in other studies, and then convert the same to Applicants' densified compositions as taught in Applicants' specification, and that the possibility that the skilled artisan may need to use the various tests set forth in Applicants' specification in order to ensure that the compacted pharmaceuticals still operates as intended does not constitute undue experimentation.

Once again, the attainment of any therapeutic and/or prophylactic effect via gene therapy and/or nucleic acid immunization **is neither routine experimentation nor predictable** as evidenced by the state and the unpredictability of the prior art at the effective filing date of the present application as already discussed above. Furthermore, none of the prior art discloses attainment of any therapeutic and/or prophylactic effect using a compacted particulate pharmaceutical composition containing a gene construct

of the presently claimed invention. Since the prior art at the effective filing date of the present application does not provide such guidance, it is incumbent upon the present application to do so. Otherwise, upon analysis of the Wands factors as already discussed above, it would have required undue experimentation for a skilled artisan to make and **use** the instant broadly claimed invention.

Accordingly, claims 15-26, 28-30, 32-37 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-31, 33-37 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellhouse et al. (WO 94/24263; IDS). **This is a new ground of rejection.**

Claims 29-31 and 33-36 are drawn to a densified particulate pharmaceutical composition formed from a lyophilized or spray-dried pharmaceutical preparation by compacting the preparation in a press, said densified composition having an average particle size in the range of about 0.1 to 250 μm mean diameter and a particle density in the range of 0.1 to 25 g/cm^3.

Claims 37, 39 and 40 are directed to a compacted particulate pharmaceutical composition formed by compacting a porous pharmaceutical preparation in a press, said compacted composition having an average particle size in the range of 0.1 to 250 μm mean diameter and a particle density in the range of 0.1 to 25 g/cm^3; a unit-dosage container for a needleless syringe comprising the same compacted particulate pharmaceutial preparation; and a method of delivering the same to a vertebrate subject.

Bellhouse et al. (WO 94/24263; IDS) disclose a method for transdermally delivering into a mammal powdered therapeutic agent particles (e.g., protein, analgesics, hormones, drugs such as insulin and calcitonin) having a size of between 0.1 and 250 μm, preferably between 1 and 50 μm, and more preferably between 10 and 20 μm, and a density in the range between 0.1 and 25 g/cm^3, preferably in the range between 0.5 and 2.0 g/cm^3, and more preferentially 1.0 g/cm^3 (page 4, lines 22-33; page 5, lines 25-9). Bellhouse et al. also teach that a substantially inert carrier may have to be included to provide the particles with the required size and mass for adequate penetration, particularly if the therapeutic agent is potent or of low density (page 5, lines 3-8). Bellhouse et al. further disclose a needleless syringe for therapeutic use, which comprises a nozzle, particles of a powdered therapeutic agent as described above, and energizing means which, on activation, deliver the particles through the nozzle at a velocity of 200 and 2,500 m/sec (page 5, lines 25-35).

Because the pharmaceutical composition taught by Bellhouse et al. has the same particle size and the same particle density, and that it is also suitable for transdermal delivery into a mammalian subject using a needleless injector, the

pharmaceutical composition of Bellhouse et al. is indistinguishable from a densified particulate pharmaceutical composition of the presently claimed invention, and so is the method of delivering the same composition to a mammal. Please, also note that where, as here, the claimed and prior art products **are identical or substantially identical, or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, Bellehouse et al. anticipate the instant claims.

Examiner would like to note that the teachings of Bellehouse et al. (WO 94/24263) are very similar to the teachings of Bellhouse et al. (US Patent 5,630,796 with an issued date of 5/20/1997), particularly should the enablement issue arise regarding to the teachings of Bellehouse et al. (WO 94/24263).

Claim 38 is rejected under 35 U.S.C. 102(e) as being anticipated by Roser et al. (US 6,331,310; IDS). **This is a new ground of rejection.**

The claim is directed to particles of a suitable size and density for transdermal delivery by needleless injection, consisting of a gene construct and a pharmaceutically acceptable excipient.

Roser et al. disclose a solid dose delivery vehicle for ballistic administration (needleless injection) for penetrating the epidermis, said vehicle contains an outer portion comprising a water soluble glassy and/**or polymeric material** having a hollow compartment therein, and an inner portion residing in the compartment, the inner portion comprising at least one stabilizing polyol and a therapeutically effective mount of at least one bioactive substance (col. 3, lines 48-54). The bioactive substance includes DNA, RNA, nucleotides encoding single genes, vectors or plasmids and others (col. 5, line 46 continues to line 39 of col. 6); and the stabilizing polyol is a carbohydrate such as trehalose, lactitol and palatinit (col. 7, lines 41-62). Suitable water soluble glass formers include lactide and lactide/glycolide copolymers, glucuronide polymers, polyorthoesters and others (col. 9, lines 28-34).

As defined by the present application, the singular form "a" and "an" include plural referents, for example "an excipient" includes mixtures of two or more excipients, and the like (page 14, lines 23-30), and the term "excipients" generally refer to substantially inert materials which are non-toxic and do not interact with other components of the composition in a deleterious manner, but do not encompass biolistic core carriers (page 16, line 33 continues to line 4 of page 17); with the term "biolistic core carrier" is defined as a carrier **on which nucleic acid is coated** in order to impart a defined particle size as well as a sufficiently high density to achieve the momentum

required for cell wall penetration (page 20, lines 13-24). The water soluble glassy and/**or polymeric material** and the stabilizing polyol in the solid dose delivery vehicle taught by Roser et al. are excipients. As such, the solid dose delivery vehicle taught by Roser et al. meets every limitation of the instant claim.

Accordingly, Roser et al. anticipate the instant claim.

Conclusions

No claims are allowed.

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER